IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
(Alexandria Division)

SMITHKLINE BEECHAM CORPORATION, d/b/a GLAXOSMITHKLINE, SMITHKLINE BEECHAM PLC, and GLAXO GROUP LIMITED, d/b/a GLAXOSMITHKLINE,	:	
Plaintiffs,	:	
v.	:	**Civil Action No. 1:07cv1008**
JON W. DUDAS, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and	:	
UNITED STATES PATENT AND TRADEMARK OFFICE,	:	
Defendants.	:	

VERIFIED AMENDED COMPLAINT

Plaintiffs SmithKline Beecham plc, SmithKline Beecham Corporation d/b/a GlaxoSmithKline, and Glaxo Group Limited d/b/a GlaxoSmithKline (collectively referred to as "GSK") for their Amended Complaint against Defendant Jon W. Dudas, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, and Defendant United States Patent and Trademark Office ("PTO"), hereby allege as follows:

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I. INTRODUCTION

1. On August 21, 2007, the Department of Commerce, Patent and Trademark Office ("PTO") published Final Rules titled "Changes To Practice for Continued Examination Filings, Patent Applications Containing Patentably Indistinct Claims, and Examination of Claims in Patent Applications." 72 Fed. Reg. 46716, 46716-46843 (Aug. 21, 2007). These Final Rules revise the rules of practice in patent applications relating to continuing applications, requests for continued examination, and for the examination of claims in patent applications.

2. These Final Rules amend, among other sections, 37 C.F.R. §§ 1.75, 1.78, and 1.114, and add 37 C.F.R. § 1.265. The changes to § 1.75 and addition of § 1.265 apply to any nonprovisional application pending on or after November 1, 2007 that has yet to receive a first Office Action on the merits. 72 Fed. Reg. at 46716. The changes to § 1.78, except for those changes to §§ 1.78(a) and 1.78(d)(1), apply to any nonprovisional application pending on November 1, 2007. *Id*. at 46717. The changes to § 1.114 apply to any application in which a request is made after November 1, 2007. *Id*. Thus, the changes affect GSK patent applications that have already been filed and are pending in the PTO. *Id*. at 46717.

3. Plaintiff GSK respectfully requests that the Court preliminarily and permanently enjoin the PTO from implementing the Final Rules on November 1, 2007 or thereafter as the Final Rules were promulgated without proper legal authority. The Final Rules are also vague, arbitrary and capricious, and prevent GSK from fully prosecuting patent applications and obtaining patents on one or more of its inventions.

4. The PTO's promulgation of the Final Rules will damage specific GSK patent applications and inventions. Presently, GSK has approximately one hundred or more pending applications in which two or more continuations or continuations-in-part have been filed, and

approximately thirty or more pending applications in which two or more continuations or continuations-in-part and a request for continued examination have been filed.

5. The PTO should be enjoined from implementing the Final Rules because Congress has not empowered the PTO to promulgate such regulations. The PTO, as a federal governmental agency, obtains its power solely at the discretion and prerogative of Congress, which is embodied in 35 U.S.C. § 2. Congress obtains its power in this area from the United States Constitution: "The Congress *shall have Power* . . . To promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries . . . ." U.S. Const. art. I, § 8, cl. 8 (emphasis added). Congress has utilized its powers and enacted laws, which do not grant the PTO the authority to restrict the number of continuing applications, requests for continued examination, or claims that may be filed. Thus, by issuing final regulations that set forth binding and mandatory rules that impose such restrictions, the PTO engaged in *ultra vires* rulemaking.

6. Under the patent laws, a patent applicant is permitted to file a continuing application so long as certain formal requirements (e.g., referring back to prior-filed applications) are met. The Final Rules, however, abrogate an applicant's ability to file continuing applications by restricting an applicant to two such applications before the applicant is required to file a petition "showing that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application." 72 Fed. Reg. at 46839. The PTO intends to apply this limit retroactively—that is, to applications that have already been filed before the effective date of the Final Rules

7. In explaining this new petition and showing requirement in response to comments, the PTO has made clear that the "could not have" evidentiary burden in almost all

cases precludes not just the grant of a petition, but also the actual filing of a petition itself. *See id*. at 46767-46779. The “could not have” standard poses a Hobson’s choice under the PTO’s rules of professional conduct, especially 37 C.F.R. § 10.85(a)(5), which bars a practitioner from knowingly making a false statement of law or fact. Violations of § 10.85(a)(5) may result in reprimand, suspension, or exclusion of practice before the PTO. *See* 37 C.F.R. § 10.131. Because the PTO construes the term “could not have” in its ordinary sense of meaning, i.e., that one could not have physically presented the amendment, evidence or argument, GSK would be at risk of violating 37 C.F.R. § 10.85(a)(5) by merely filing a petition. This conflict renders compliance with the PTO’s new petition requirement extremely difficult, if not impossible, because it is unclear how an applicant and its counsel could satisfy both the applicable ethical obligations as well as the “could not have” standard. As a result, the PTO’s petition and showing requirement represents a regulatory trap, except in the case where the PTO requests data from an applicant and the applicant diligently acquires data demonstrating unexpected results and desires to submit the data to rebut a new PTO rejection that the claims are obvious over the prior art.

8. The patent laws also allow applicants to file a request for continued examination (“RCE”) of an application and require that the PTO continue such examination when requested to do so. 35 U.S.C. § 132. The Final Rules, however, impose substantive restrictions on an applicant’s ability to file such requests for continued examination and, in doing so, the Final Rules exceed the PTO’s authority. Indeed, the Final Rules allow an applicant only one RCE before requiring the applicant to submit a petition showing that “the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application . . . .” 72 Fed. Reg. at 46841-42. Again, the PTO will be applying this provision retroactively to pending applications. As with the proposed limit on continuations, GSK, along

with many other parties, submitted comments to the PTO demonstrating that, if the agency imposed any restrictions upon requests for continued examination, it would be acting beyond its statutory authority and harming important intellectual property interests.

9. The patent laws specifically allow an applicant to file "one or more claims," so long as the claims meet the requirements for patentability. 35 U.S.C. § 112, ¶ 2. In sharp contrast, the Final Rules impose unlawful restrictions and limits on the number of claims an applicant may submit before being required to submit an onerous "examination support document." 72 Fed. Reg. at 46836-37. The PTO will apply this new restriction and limitation retroactively to any application pending that has yet to receive a first Office Action on the merits from the PTO. In substantively restricting an applicant's rights to claim their inventions, the PTO has exceeded its authority and will cause affected applicants irreparable harm.

10. In another pending suit in this Court, *Tafas vs. Dudas, et al.* Civil Action No. 1:07cv846, Plaintiff Tafas has alleged that the PTO's promulgation of the Final Rules will cause him harm. Defendants in the *Tafas* litigation, which are the same as the present Defendants, filed a Partial Motion to Dismiss and a Memorandum in Support of Defendants' Partial Motion to Dismiss on October 4, 2007. While the Tafas allegations and the Defendants' responses to those allegations are distinct, separate and independent from GSK's present allegations, GSK refers herein to certain aspects of Defendants' Memorandum in Support for ease of reference for the Court.

11. Specifically, the Director and the PTO have taken the position that one may not be able to establish harm caused by the Final Rules except by demonstrating specific examples of harm caused to pending patent applications. While GSK amply meets this burden, the Director's and the PTO's position is convenient but incorrect, because it runs contrary to the

two-part ripeness test established in *Abbott Laboratories v. Gardner*, 387 U.S. 136 (1967), which permits preenforcement review of agency regulations where the questions presented are fit for judicial review and would pose a hardship to regulated parties. Here, the PTO's authority to promulgate rules is both granted and limited by 35 U.S.C. § 2. The PTO "may establish regulations, **not inconsistent with law**, which shall govern the conduct of proceedings in the Office." 35 U.S.C. § 2(b) (2006) (emphasis added). Under this single statutory grant of rulemaking power, the PTO can only promulgate rules that fall squarely within the bounds of established statutory patent law. It has exceeded its authority in promulgating the Final Rules, thereby posing a fit question for preenforcement review under *Abbott Laboratories*.

12. The Final Rules clearly apply to a domain of regulated parties such as GSK because GSK regularly applies for patents using continuing applications and requests for continued examination, as well as requests the examination of multiple claims in its patent applications. The Final Rules would require GSK "either to expend non-recoverable resources in complying with a potentially invalid regulation or to risk subjection to costly enforcement processes," *Seegars v. Gonzales*, 396 F.3d 1248, 1253 (D.C. Cir. 2005), and hence pose a hardship to GSK that permits preenforcement review. In *Abbott Laboratories*, the Supreme Court permitted the preenforcement review of Food and Drug Administration labeling and advertising regulations for drugs. Here, the legal questions presented threaten not only added costs from compliance with ancillary marketing restrictions, but whether the life-saving drugs innovated by GSK and other similarly situated members of the pharmaceutical industry will be invented in the first place, given the changes to the patenting system that the PTO seeks to impose.

13. On September 7, 2007, the House of Representatives passed H.R. 1908. Section 14 of H.R. 1908 amends Title 35 to add § 2(c)(6), which grants the PTO "authority to promulgate regulations to insure the quality and timeliness of applications and their examination, including specifying circumstances under which an application for patent may claim the benefit under Sections 120, 121 and 365(c) of the filing date of prior filed application for patent." Section 14 of H.R. 1908 further states that any regulations passed under Section 2(c)(6) can not take effect before the end of sixty days after the Director submits to each House of Congress a copy of the regulation. If a joint resolution of disapproval is passed, the regulation shall not become effective. The Senate is considering S. 1145, which unlike H.R. 1908, rightly does not include a grant of similar rulemaking authority to the PTO. Based on this legislative action, it is clear that: (i) While the House of Representatives couches the provision as a clarification of existing law, Congress has not yet granted the PTO the authority to make rules of practice that restrict continuing applications—if Congress had already given the PTO such authority in 35 U.S.C. § 2, then Section 14 of H.R. 1908 would be redundant and meaningless; (ii) The House of Representatives takes the position that the PTO should not promulgate such rules until Congress has been given 60 days to consider and perhaps disapprove them; (iii) The Senate correctly and appropriately has not followed the House of Representatives to date in approving a bill that grants the PTO this rulemaking authority; and (iv) The issue of PTO rulemaking authority is still subject to significant congressional debate, has not been agreed upon, and, indeed, may never be agreed to in the future. The PTO cannot bypass the political process by promulgating rules when Congress has not given that rulemaking authority to the PTO.

14. The Final Rules also pose an unconstitutional arbitrary and capricious regulatory taking of GSK's patent and patent application property rights. Patents and patent applications

are constitutionally protected private property. *See* 35 U.S.C. § 261; *Consolidated Fruit-Jar Co. v. Wright*, 94 U.S. 92, 96 (1876) ("A patent for an invention is as much property as a patent for land."); *Winchester v. Commissioner*, 27 B.T.A. 798, 1933 WL 231, at 3 (Bd. Tax. App. 1933) ("It is now well settled that patent applications are property."); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002-04 (1984) (finding that intellectual property, such as a trade secret, is constitutionally protected private property). By imposing arbitrary restrictions on GSK's ability to prosecute its patent applications, the Final Rules diminish greatly the value of GSK's pending and future patent applications by depriving GSK the ability to claim fully and completely its inventions, resulting in an unconstitutional taking. The PTO has acted arbitrarily and capriciously in failing to adequately consider such issues in the rulemaking process.

15. The Final Rules are so vague that they are incapable of being complied with and do not put GSK on sufficient notice of what it must do to comply. Under new 37 C.F.R. § 1.75(b)(1), if an application contains more than five independent claims and/or twenty-five total claims, an applicant must file an examination support document ("ESD") in compliance with new 37 C.F.R. § 1.265. 72 Fed. Reg. at 46836.

16. Newly created § 1.265 sets forth the requirements of an ESD, one of which, § 1.265(a)(1), requires that the applicant perform a preexamination search. *Id*. at 46842. Rule 1.265(b) sets forth requirements of a preexamination search as including the searching of "U.S. patents and patent application publications, foreign patent documents and non-patent literature." *Id*.

17. Newly added § 1.265(b), however, does not provide any metes or bounds on the scope of the search and, as a result, GSK has no idea how to comply with this regulation. For instance, neither the rule nor the comments indicate whether the applicant must conduct

electronic searches, manual searches, or both; in which countries' databases the applicant must search; or which libraries it must search. Certainly, the cost of searching could be quite large and the rule does not set forth an expense cap or limitation. In light of the vagueness of § 1.265, GSK does not know how to comply with the rule and, therefore, the PTO should be enjoined from implementing the rule. The PTO has issued guidance documents, but these not regulations and do not cure the vagueness of the ESD requirement.

18. Newly amended § 1.75(b) also states that "[m]ore than one claim may be presented provided they differ substantially from each other and are not unduly multiplied." 72 Fed. Reg. at 46836. The term "not unduly multiplied" is also vague and does not put GSK on sufficient notice of what is permissible. This kind of vague language can impermissibly be used at the discretion of the PTO to mean almost anything, and therefore is not a well-defined rule capable of compliance or consistent with the rational organization of business activities. Furthermore, the lack of clarity in the Final Rules will multiply the nonrecoverable compliance costs that GSK will experience under the new system the PTO seeks to establish without a statutory delegation for doing so.

II. JURISDICTION AND VENUE

19. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338, and 1361.

20. GSK has standing to bring this suit because it is specifically and personally harmed by the Final Rules. Indeed, GSK's standing is self-evident because it is a frequent user of the patent system and a directly regulated party. GSK is not an isolated inventor that may never innovate again, and GSK is not seeking to represent the interests of third-party inventors.

21. This matter is ripe because the issues GSK presents for review meet the *Abbott Laboratories* fitness and hardship requirements, and because GSK also has pending patent applications that are affected by the Final Rules.

22. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e).

a. The Director's principal office and the PTO's headquarters are located in Alexandria, Virginia pursuant to 35 U.S.C. § 1(b).

b. The PTO conducted its *ultra vires* and unconstitutional rulemaking activities in Alexandria, Virginia at its headquarters and solicited comments in Alexandria, Virginia. Hence, the events giving rise to this action occurred in Alexandria, Virginia.

23. This case arises under causes of action created by the judicial review provisions of the Administrative Procedure Act, 5 U.S.C. § 701, *et seq.*

24. Proper forms of relief in this action include, but are not limited to, the following:

a. issuing preliminary and permanent injunctions under 5 U.S.C. § 703;

b. issuing declaratory relief under 5 U.S.C. § 703 and 28 U.S.C. §§ 2201-2202;

c. holding unlawful and setting aside the PTO's action (i.e., issuing a vacatur remedy) under 5 U.S.C. § 706(2); and

d. compelling the PTO to perform its duty under 28 U.S.C. § 1361.

III. THE PARTIES

25. Plaintiff SmithKline Beecham plc is a public limited company organized under the laws of England and Wales with its principal place of business at 980 Great West Road, Brentford, Middlesex, TW89GS, England.

26. Plaintiff SmithKline Beecham Corporation, doing business as GlaxoSmithKline, is a Pennsylvania corporation having its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19102.

27. Plaintiff Glaxo Group Limited, doing business as GlaxoSmithKline, is a company organized and existing under the laws of England and having an office and place of business at Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex, UB6 ONN, United Kingdom.

Plaintiffs SmithKline Beecham plc, SmithKline Beecham Corporation, and Glaxo Group Limited are hereinafter collectively referred to as "GlaxoSmithKline" or "GSK."

28. Defendant PTO is an administrative agency of the United States Department of Commerce. The PTO's headquarters is located in Alexandria, Virginia. The PTO is responsible for granting and issuing patents and registering trademarks and disseminating information to the public regarding patents and trademarks. Among other things, the PTO is authorized to establish regulations "not inconsistent" with the patent laws which "govern the conduct of proceedings" before the PTO.

29. Defendant Jon W. Dudas is the Under Secretary of Commerce for Intellectual Property and the Director of the PTO ("the Director") and is named in his official capacity. Under 35 U.S.C. § 3(a), the Director is charged with providing policy direction and management supervision for the PTO. The Director is also responsible for issuing patents and registering trademarks.

30. GSK researches, develops, tests, and markets life-saving medicines that treat some of the worst diseases, including cancer, cardiovascular disease, respiratory diseases such as asthma and chronic obstructive pulmonary disease, HIV, Alzheimer's, depression, and diseases of the emerging world such as malaria and tuberculosis. To get to the point of marketing these drugs, GSK spends hundreds of millions, and typically over one billion dollars, per new drug on human clinical trials where the entirety of GSK's investment is at risk due to the uncertainty of the clinical trial process, which results in many drugs never reaching the marketing phase. GSK also develops preventative medicines such as pediatric vaccines, cancer vaccines, and deadly bacteria vaccines and is currently in clinical trials to create preventative medicines for prostate cancer, melanoma and cervical cancer. Under the current patent system and its well-established

incentives, GSK has been able to bring many innovative and beneficial drugs to market. For example, over the past several years, GSK has brought to the American public Zofran, for alleviation of nausea and vomiting associated with chemotherapy and radiotherapy for cancer, Valtrex, for management of herpes simplex and herpes zoster, Advair for the prophylactic treatment of asthma and other airway obstruction disorders, and Coreg, for the treatment of mild-to-severe chronic heart failure. GSK is proud of its recent launch in the United States of Tykerb for the treatment of advanced stage and metastatic breast cancer after over ten years of research.

31. GSK undertakes enormous efforts to bring new drugs and products to market. The scientific research and discovery of a new drug and the following clinical development often takes a decade or more of hard work and a billion dollars in completely at-risk investment. The research and development of drugs is fraught with many hurdles, ultimately leading to thousands of rejected drugs (and wasted money) for each successful drug to market. Joseph A. Dimasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. Health Econ. 151, 159-60 (2003); *see also* Christopher P. Adams & Van V. Brantner, *The Real Cost of Drug Development*, Drug Development 2006 23, 23-24 (2006), available at http://www.touchbriefings.com/pdf/1842/Chris_Adams.pdf.

32. GSK's drug products protect and support the health and life of American citizens. GSK has expended tremendous research investments to bring those drugs to market. The current patent laws encourage GSK to invest in the discovery and development of those drugs, as well as new drugs currently under development, by providing robust patent protection. GSK's drug research necessarily requires a large, up-front, at-risk investment. That research involves sophisticated, high-level sciences, including organic chemistry and molecular biology, which require significant resources to generate innovative drugs. Further, the discovery and

development of those drugs through the time of approval can take up to ten years or more. During that time, additional or confirmatory information is often gathered about the drugs that GSK should be able to use to obtain strong patent protection. Without the guarantee of adequate patent protection, GSK's ability to innovate is compromised because it cannot afford to undertake the enormous research investments necessary to bring these drugs to market.

33. The Final Rules arbitrarily limit the ability to claim all aspects of new medical inventions and discoveries thereby reducing the incentive to innovate. That harms not just GSK; it causes substantial harm to the public interest by threatening the future health of American citizens.

IV. SUMMARY OF DISPUTE AND HARM CAUSED BY THE FINAL RULES

A. Continuation Patent Applications And The Changes Under The New Rules

34. An inventor has a statutory entitlement to a patent unless the invention that is the subject of the application for the patent is not new or is obvious. 35 U.S.C. §§ 102-03. To obtain a patent, an inventor must file a written application that contains a specification, an oath and "one or more" claims. 35 U.S.C. §§ 111-12.

35. The date of filing of each patent application is critically important. The applicant's entitlement to a patent, e.g., novelty under 35 U.S.C. § 102 and non-obviousness under 35 U.S.C. § 103, will be judged from the earliest filing date to which the application is entitled. By obtaining the earliest possible filing date, an applicant may establish that its patent application was filed before a similar application filed by someone else. The filing date also

allows an applicant to demonstrate that its application was filed before the date of publication of information (called prior art) that would have to be considered in evaluating patentability.[1]

36. 35 U.S.C. § 120 provides that a patent application filed by an inventor for an invention previously disclosed in a pending patent application "shall have the same effect, as though filed on the date of the prior application," if, among other things, it contains a specific reference to the prior application. Section 120 allows inventors to file chains of patent applications that relate back to a first filed application and entitle the later applications to the benefit of the filing date of the first filed application for each application in the chain. The applications filed after the first application are known as "continuation" applications. Thus, a continuation patent application is a patent application that stems from, and claims the benefit of the filing date of, an earlier-filed patent application. *See* 4A Donald S. Chisum, *Chisum on Patents* § 13.03 (2007). A continuation application contains the same disclosure as the original application.

37. The priority filing date is critical to GSK because it sets the stake in the ground on prior art references from which the PTO will analyze the patentability of the patent claims during prosecution (and, potentially, in later litigation). If the priority filing date is lost because GSK cannot claim the benefit of the filing date in a later-filed application, the later-filed application will only be entitled to its actual filing date, and the later-filed application will be analyzed against prior art that became available between the earlier-filed application and the later-filed application. In such situations, if the earlier-filed application is published as is often the case

[1] Defendants in the *Tafas* litigation provided a summary of the patent application process on pages 4 through 8 of their Memorandum in Support of Defendants' Partial Motion to Dismiss. GSK provides a copy of Defendants' summary as Attachment A to this Complaint for the Court's convenience.

under 35 U.S.C. § 122, then the earlier-filed application itself may become prior art against the later-filed application.

38. There have historically been numerous valid reasons to file continuation applications of earlier-filed patent applications in a manner that advances patent prosecution yet maintains the benefit of that critical early stake in the ground. For example, GSK files continuation applications to differentiate its invention from the prior art, following the unsuccessful submission of arguments that the patent examiner has not established a *prima facie* case of obviousness. GSK also files continuation applications containing rejected claims to present evidence of unexpected advantages of an invention when that evidence may not have existed at the time of an original rejection. *See, e.g., Symbol Techs., Inc. v. Lemelson Med., Educ. & Research Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005) (stating that it is proper to file a continuation application to submit evidence of unexpected advantage that did not exist at the time of the rejection). GSK also files continuation applications to add new claims directed to subject matter that is disclosed in the application, but which has not been claimed in a prior application for which examination has closed on the merits. The PTO has indicated that all the foregoing bases would be insufficient to carry the applicant's burden of showing that the argument or evidence "could not have been submitted earlier" under the final rules. 72 Fed. Reg. at 46772-77. The PTO has made these pronouncements despite the fact that the Federal Circuit has stated that GSK, or any applicant, "may also refile an application even in the absence of any of these reasons, provided that such refiling is not unduly successive or repetitive." *See Symbol Techs.*, 422 F.3d at 1385.

39. In the past, GSK has also filed continuations to disclose new prior art, often times, as a result of the receipt of a "Search Report" from a foreign patent office during the examination

of a related foreign patent application. Applicants may submit references cited by a foreign patent office in a related application or face a later charge of inequitable conduct for failure to comply with the duty to disclose material information to the PTO during prosecution. *See, e.g., Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 (Fed. Cir. 1995) (finding inequitable conduct based on failure to submit references cited in a search report from the European Patent Office). The PTO, however, has indicated that, under the Final Rules, it will not accept a petition based on the disclosure of new prior art. 72 Fed. Reg. at 46773-74.

40. The Final Rules remove GSK's right to obtain the filing date of the first filed application for additional applications by limiting an applicant to two continuation applications before the applicant is required to file a petition "showing that the amendment, argument, or evidence sought to be entered **could not have** been submitted during the prosecution of the prior-filed application." 72 Fed. Reg. at 46839 (emphasis added). The PTO has indicated that the following reasons for filing continuation applications, which were all normal, customary, sanctioned and accepted reasons for filing continuations prior to the Final Rules, are no longer adequate to support a petition: the applicant attempts to submit "newly discovered prior art" (Response to Comment 85), the examiner's interpretation of the claims is unusual and only recently understood by the applicant or the examiner changes his or her interpretation of claim language (Response to Comment 87), applicants have recently discovered a commercially viable product, financial resources, useful subject matter, a competing product, or similar or parallel technology on the market (Response to Comment 91), or the applicant becomes disabled for a lengthy time during the pendency of the application (Response to Comment 100). *Id.* at 46773-77.

41. The PTO intends to apply this limit retroactively—to applications that have already been filed before the effective date of the Final Rules. The PTO discriminates against already pending applications that include two or more continuations or continuations-in-part by arbitrarily allowing only "one more" continuation application (before an applicant is required to file a petition and showing).

42. In explaining the requirement in response to comments, the PTO has made clear that the "could not have" evidentiary burden in almost all cases precludes not just the grant of a petition, but also the actual filing of a petition itself. *See id*. at 46767-46779. For example, the "could not have" standard creates a dilemma for applicants and their counsel under 37 C.F.R. § 10.85(a)(5) in the PTO's rules of professional conduct, which bars a practitioner from knowingly making a false statement of law or fact. The PTO construes the term "could not have" in its ordinary sense of meaning, i.e., that one could not have physically presented the amendment, evidence or argument, and, as a result, GSK would be at risk of violating 37 C.F.R. § 10.85(a)(5) by merely filing a petition. This conflict renders compliance with the PTO's new petition requirement extremely difficult, if not impossible, because it is unclear how an applicant and its counsel could satisfy both the applicable ethical obligations as well as the "could not have" standard. As a result, the PTO's petition and showing represents a regulatory trap, except in the case where the PTO requests data from an applicant and the applicant diligently acquires new data demonstrating unexpected results and desires to submit the data to rebut a new PTO rejection that the claims are obvious over the prior art.

B. Historical Background Regarding Continuation Applications

43. As early as 1863, the Patent Act was understood to allow an applicant to file continuation patent applications. *See Godfrey v. Eames*, 68 U.S. 317, 325-26 (1863) (in interpreting the act of 1839, the Supreme Court recognized that "if a party choose to withdraw

his application for a patent . . . intending at the time of such withdrawal to file a new petition, and he accordingly do so, the two petitions are to be considered as parts of the same transaction, and both as constituting one continuous application . . .”).

44. During the ensuing years, the law did not limit the number of continuation applications that may be filed. In discussing continuation applications, William Robinson’s 1890 patent treatise noted that “[i]t is immaterial how many of these substituted applications may be filed, or for how long a period such efforts to obtain a patent may be continued.” 2 William C. Robinson, *The Law of Patents for Useful Inventions* § 581, at 204 (reprinted, 1972); *see also* 1 Walter F. Rogers, *The Law of Patents* 21 (1914) (“[N]o number of successive applications indicates an intention to abandon, . . . in reference to the question of abandonment, all such may be regarded as one application, the ones subsequent to the first being known as ‘continuing’ applications.”).

45. In enacting 35 U.S.C. § 120 in the Patent Act of 1952, Congress codified the existing case law regarding continuations. According to the legislative history, Section 120 represented “present law not expressed in the statute, except for the added requirement that the first application must be specifically mentioned in the second.” Senate Report No. 1979, June 27, 1952 (accompanying H.R. 7794), at 2413.

46. 35 U.S.C. § 120, as enacted in 1952, stated that:

> An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States by the same inventor shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

Act of July 19, 1952, Pub. L. No. 593, ch. 950, § 120, 66 Stat. 800, *reprinted in* 1952 U.S.C.C.A.N. 761.

47. After 35 U.S.C. § 120 was enacted, the Court of Customs and Patent Appeals—the predecessor court to the Federal Circuit—stated that the PTO could not limit the number of continuing applications that an applicant could file. *See In re Henriksen*, 399 F.2d 253, 254 (C.C.P.A. 1968). The court stated that a patent examiner had "no statutory basis for fixing an arbitrary limit to the number of prior applications through which a chain of co-pendency may be traced to obtain the benefit of the filing date of the earliest of a chain of co-pending applications, provided applicant meets all the other conditions of the [§120] statute." *Id.*

48. The PTO has stated that *Henriksen* "established that the Office cannot deny an applicant the benefit of the filing date of his earliest filed case no matter how many intervening continuing applications when no other pertinent facts are involved." *Ex parte Hull*, 191 U.S.P.Q. 157, 159 (Pat. & Tr. Office Bd. App. 1975).

49. The Court of Customs and Patent Appeals also indicated that only Congress can limit the number of continuation applications. Specifically, the court stated that, "it is for the Congress to decide, with the usual opportunity for public hearing and debate, whether such a restriction [on continuation practice] . . . is to be imposed." *Henriksen*, 399 F.2d at 262. Further, in 1977, the Court of Customs and Patent Appeals reiterated that limiting "continuing applications is a matter of policy for the Congress . . . ." *In re Hogan*, 559 F.2d 595, 604 n.13 (C.C.P.A. 1977).

50. After *Henriksen*, courts have continued to interpret Section 120 very broadly. *See In re Bauman*, 683 F.2d 405, 406-407 (C.C.P.A. 1982) (denying the PTO's ability to "require recognition of a nonstatutory exception to the clear language of § 120"); *Transco Products Inc.*

v. Performance Contracting, Inc., 38 F.3d 551, 556-557 (Fed. Cir. 1994) (not requiring a patent applicant to update its "best mode" disclosure when filing a continuation application, because it was not required under § 120's "plain and unambiguous meaning").

51. In 1999, Congress contemplated and altered the scope of the PTO Director's discretion under Section 120 to deny an application the benefit of a priority. *See* Pub. L. No. 106-113, § 4503(b)(1), § 120, 113 Stat. 1501, 1501A-563 to 1501A-564 (1999). Specifically, Congress added the following paragraph to Section 120:

> No application shall be entitled to the benefit of an earlier filed application under this section unless an amendment containing the specific reference to the earlier filed application is submitted at such time during the pendency of the application as required by the Director. The Director ***may consider*** the failure to submit such an amendment within that time period as a waiver of any benefit under this section. The Director ***may establish procedures***, including the payment of a surcharge, to accept an unintentionally delayed submission of an amendment under this section.

Id. (emphasis added). Thus, Congress explicitly granted the PTO *limited* authority to "empower the Director to: (1) establish a time by which the priority of an earlier filed United States application must be claimed; (2) consider the failure to meet that time limit to be a waiver of the right to claim such priority; and (3) accept an unintentionally late claim of priority subject to the payment of a surcharge." 145 Cong. Rec. S14,719 (daily ed. Nov. 17, 1999). Congress did not grant the PTO any other discretionary powers.

C. GSK's Use Of The Patent Application Process During Drug Research And Development

52. GSK undertakes enormous efforts to bring new drugs and products to market. The scientific research and discovery of a new drug and the following clinical development often takes a decade or more of hard work and a billion dollars in completely at-risk investment. The research and development of drugs is fraught with many hurdles, ultimately leading to thousands

of rejected drugs (and wasted money) for each successful drug to market. Dimasi et. al., *supra*, at 159-60; *see also* Adams & Brantner, *supra*, *The Real Cost of Drug Development*, at 23-24.

53. The FDA imposes substantial requirements and conditions on therapeutic drug products, including lengthy and detailed laboratory and clinical testing prerequisites, sampling activities, reporting requirements, and other costly and time-consuming procedures. These, along with other scientific and regulatory requirements and the extreme complexities associated with pharmaceutical research and technology, explain why so many promising drug candidates are ultimately rejected and so few get to market.

54. These requirements also explain why the average discovery and development life cycle for a new drug product is between 10 and 12 years. *See* DiMasi et al., *supra*, at 164 (noting that the average time between the commencement of phase I clinical trials and FDA approval can exceed 10 years). Further, this strict regulatory environment also explains, in part, why the average financial cost to GSK to discover and develop a new drug can exceed $1 billion. *See* DiMasi et al., *supra*, at 180 (finding, in year 2000, that the average research and development cost for 68 randomly selected new drugs was $802 million); Christopher P. Adams & Van V. Brantner, *Estimating the Cost of New Drug Development: Is it Really $802m?* 25 Health Affairs 420, 420-428 (2006) (concluding that $802 million is likely an underestimate of the actual cost of new drug development); Adams & Brantner, *The Real Cost of Drug Development*, *supra*, at 24 (finding the average cost of developing a new drug to be over $1 billion).

55. GSK relies heavily on patents. Patents play an essential role in encouraging GSK to continue to invest in the invention and discovery of new drugs. GSK relies on patent protection for drug products successfully brought to market to finance their overall investment in

research and development. This investment encompasses losses incurred in failed drug development efforts. The current laws provide robust patent protection, which allows GSK to protect their investments with relatively few patents on new chemical entities.

56. Without strong patent protection, a new drug would immediately be copied and sold by others who did not incur the billions of dollars in research investments borne by an innovator company like GSK. Without patent protection or with inadequate protection, GSK cannot afford to undertake the huge investment in research and development necessary to bring drugs—including drugs that treat the most serious and life-threatening diseases—to market. In fact, one report estimates that pharmaceutical investment in innovation may "decrease by approximately 60%" without adequate patent protection. Federal Trade Commission, *The Proper Balance of Competition and Patent Law Policy* 11 n.48 (2003).

57. Because of this long and arduous process, GSK often identifies a group of related potential lead drug candidates (a "genus" of compounds) upon which it files patent applications at a very early stage, often before commencing clinical trials. At the time it files its initial application, GSK may have little idea which of these drug candidates will make it through the battery of efficacy and toxicity testing, including human testing. In this typical case, GSK proceeds with patent prosecution on one of the drugs in the genus, and then many years later, may find that that drug was not suitable for commercial administration to patients, and then it needs to go back and begin to prosecute a second lead compound out of the earlier-filed case. However, by that time, GSK may have used up several continuation applications on the patent prosecution of the first drug. Under the Final Rules, in this circumstance GSK cannot go back and select a second lead candidate out of the genus because it "could [] have submitted" the claims earlier—however, at that point, it was unnecessary because GSK did not know that the

first test candidate would fail. In this case, GSK and the public would lose the benefit of a potential great drug, because GSK has to walk away from the second lead candidate since it would have no patent protection. This is not a theoretical problem; this is the typical business reality of drug development at GSK. Since the drug research and development process often takes ten or more years, it is critical that GSK be able to file continuation applications as necessary that can maintain the benefit of the early filing date, the stake in the ground, against third party references that could be used to deny later patent protection.

58. Confirmation of this business model is the fact that in a measured time period of 1996-98, only 7.8% of issued patents were pharmaceutical patents, while pharmaceutical applications accounted for 22% of filed continuations and continuations-in-part. John R. Allison & Mark A. Lemley, *The Growing Complexity of the United States Patent System*, 82 B.U. L. Rev. 77, 119-20 n.99 (2002). This is because of the reality of the lengthy drug research process.

D. PTO's Limited Rulemaking Authority

59. The PTO's rulemaking authority derives from 35 U.S.C. § 2, which grants the PTO the authority to:

> establish regulations, not inconsistent with law, which—
>
> (A) shall govern the conduct of proceedings in the Office;
>
> (B) shall be made in accordance with section 553 of title 5;
>
> (C) shall facilitate and expedite the processing of patent applications, particularly those which can be filed, stored, processed, searched, and retrieved electronically, subject to the provisions of section 122 [35 U.S.C. § 122] relating to the confidential status of applications; . . . .

35 U.S.C. § 2(b)(2).

60. The Patent Act confines the PTO's powers to regulating internal procedures in practice before the agency. *See* 35 U.S.C. § 2(b)(2). Section 2(b)(2) does not confer general rulemaking power on the PTO to interpret the Patent Act.

61. Conspicuously absent from the precise enumeration of proper subjects for rulemaking in the six sub-provisions of Section 2(b)(2)(A) through (F) is the conferral of any type of power to interpret any substantive provisions of the Patent Act. For this reason, the Federal Circuit, not surprisingly, has held that the *broadest* rulemaking power the PTO possesses is Section 2(b)(2)(A), which allows the PTO merely to issue rules governing "the conduct of proceedings *in the Office*." (emphasis added). Thus, overall, the Patent Act does not confer upon the PTO any power to decide questions that extend beyond matters of internal proceedings at the PTO.

62. The Federal Circuit has long highlighted that Section 2(b)(2) does not confer on the PTO the power to issue substantive rulemakings. *See Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) ("As we have previously held, the broadest of the PTO's rulemaking powers—35 U.S.C. § 6(a) [now 35 U.S.C. § 2(b)(2)(A)]—authorizes the Commissioner to promulgate regulations *directed only to* the conduct of proceedings in the PTO; it does NOT grant the Commissioner the authority to issue substantive rules." (citations omitted) (emphasis in original)). The soundness of this conclusion is also confirmed by the proviso that initiates the enumeration of the PTO's rulemaking powers—the PTO can only establish regulations that are "not inconsistent with law." *See* 35 U.S.C. § 2(b)(2)(A). The Federal Circuit has reaffirmed its continued agreement with the *Merck* holding as recently as 2003 in *Eli Lilly & Co. v. Board of Regents of University of Washington*, 334 F.3d 1264, 1269 n.1 (Fed. Cir. 2003).

63. In 1999, Congress added Section 2(b)(2)(C), empowering the PTO to issue regulations that would "facilitate and expedite the processing of patent applications." *See* Fiscal Year 2000 Consolidated Appropriations Act, Pub. L. No. 106-113, 113 Stat. 1501, 1501A-573 (1999). But, when Congress added that provision, it did not express any intent to overrule *Merck* and its progeny in the Federal Circuit. Instead, Congress merely moved former Section 6(a) of the Patent Act to Section 2(b)(2)(A). The structural logic of doing so is obvious: Current Section 2(b)(2)(A) is the most broadly framed enumerated power, and thus naturally appears as the first grant of authority describing PTO rulemaking powers. Section 2(b)(2)(A) is then followed structurally (after Section 2(b)(2)(B) detours momentarily to make clear that all PTO rulemakings are to be governed by the Administrative Procedure Act) by successively narrower grants of rulemaking authority. Thus, viewing Section 2(b)(2) as a whole, as edited by the legislature in 1999, Congress effectively ratified *Merck*, confining the PTO's rulemaking powers purely to internal matters of procedure that would be non-substantive in nature. Thus, the addition of Section 2(b)(2)(C), as a subsidiary heading of power, did not expand the PTO's rulemaking authorities.

64. Since 1999, Congress has twice proposed, but failed to pass into law, legislation that would have expanded PTO's rulemaking authority. On June 8, 2005, the House of Representatives introduced the Patent Reform Act of 2005, H.R. 2795, which would have granted the Director the power to promulgate regulations concerning continuation practice. *See* H.R. 2795 § 8. More broadly, the Patent Reform Act of 2006, S. 3818, introduced on August 3, 2006 in the United States Senate, contained a provision that would have allowed the PTO the authority to issue rulemakings to "carry out" the Patent Act. *See* S. 3818 § 6(e).

65. On September 7, 2007, the House of Representatives passed H.R. 1908. Section 14 of H.R. 1908 amends Title 35 to add § 2(c)(6), which grants the PTO "authority to promulgate regulations to insure the quality and timeliness of applications and their examination, including specifying circumstances under which an application for patent may claim the benefit under sections 120, 121 and 365 (c) of the filing date of prior filed application for patent." Section 14 of H.R. 1908 further states that any regulations passed under Section 2(c)(6) can not take effect before the end of sixty days after the Director submits to each House of Congress a copy of the regulation. If a joint resolution of disapproval is passed, the regulation shall not become effective. The Senate is considering S. 1145, which unlike H.R. 1908, rightly does not include a grant of similar rulemaking authority to the PTO. Based on this legislative action, it is clear that: (i) While the House of Representatives couches the provision as a clarification of existing law, Congress has not yet granted the PTO the authority to make rules of practice that restrict continuing applications—if Congress had already given the PTO such authority in 35 U.S.C. § 2, Section 14 of H.R. 1908 would be redundant and meaningless; (ii) The House of Representatives takes the position that the PTO should not promulgate such rules until Congress has been given 60 days to consider and perhaps disapprove them; (iii) The Senate has not followed the House of Representatives to date in approving a bill that grants the PTO this rulemaking authority; and (iv) The issue of PTO rulemaking authority is still subject to significant Congressional debate, has not been agreed upon, and, indeed, may never be agreed to in the future. The PTO cannot bypass the political process by promulgating rules when Congress has not given that rulemaking authority to the PTO.

E. Section 112

66. The quid pro quo for the Patent Act's grant of exclusivity is that the applicant must disclose its invention in the manner provided in 35 U.S.C. § 112 so that the public benefits

from the applicant's scientific advance and, using that foundation, can further develop the technology. The application must contain, among other things, a specification containing a written description that enables one of ordinary skill in the art to make and use the invention, the best mode of practicing the invention, and "one or more claims." 35 U.S.C. § 112, ¶¶ 1-2.

67. Moreover, the claims must "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." *Id.* Hence, Congress' directive is merely that claims must be definite. Beyond that, Congress did not impose any artificial limits on the number of claims that could be made in a patent application. Thus, Section 112 reinforces the general denial to the PTO of substantive rulemaking power. For substantive patent law purposes, the Patent Act typically *regulates* the PTO; it does not grant regulatory power to the PTO.

68. As a matter of form, a "claim may be written in independent or, if the nature of the case admits, in dependent or multiple dependent form." 35 U.S.C. § 112, ¶ 3. Further requirements for specifying in dependent form and in multiple dependent form are provided. *See id.* § 112, ¶¶ 4-5. The level of detail in these requirements does not suggest that Congress intended the PTO to supplement these requirements with its own rules.

F. Section 132 Practice

69. Section 132(b) of Title 35 requires the Director and the PTO to continue examination of applications when an applicant so requests. Specifically, 35 U.S.C. § 132(b) provides that "[t]he Director ***shall*** prescribe regulations to provide for the continued examination of applications for patent ***at the request of the applicant***." (emphasis added).

70. To promote efficiency in the examination process and to avoid needless appeals of claim rejections by examiners at the PTO, Congress amended 35 U.S.C. § 132(b) to allow for requests for continued examination of an application. Congress has not authorized the PTO to

limit the number of RCEs that an applicant may file, as Section 132(a) states that the PTO "shall" continue examination upon request. *See* 35 U.S.C. § 132(a) ("[I]f after receiving such notice [of rejection or objection], the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined."). Section 132(b) provides that the "Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant." By its own terms, Section 132(b) means that regulations must be issued that allow for continued examination at an applicant's request. Section 132(b), particularly when read in conjunction with Section 132(a), does not authorize the Director to restrict RCEs.

G. The Revised Rules

i. The PTO's Proposed Rules

71. On January 3, 2006, the PTO issued two separate notices of proposed rule making in the Federal Register.

72. The first Notice of Proposed Rule Making was entitled "Changes to Practice for Continuing Applications, Requests for Continuing Patent Applications, Requests for Continued Examination Practice, and Applications Containing Patentably Indistinct Claims." 71 Fed. Reg. 48 (Jan. 3, 2006) ("NPRM 1").

73. The second Notice of Proposed Rule Making is entitled "Changes to Practice for the Examination of Claims in Patent Applications." 71 Fed. Reg. 61 (Jan. 3, 2006) ("NPRM 2").

a. In NPRM 1, The PTO Proposed Restricting Applicants To A Single Continuing Application And A Single Request For Continued Examination

74. In NPRM 1, the PTO proposed restricting applicants to a single continuing application before having to file a petition "showing to the satisfaction of the Director that the

amendment, argument, or evidence could not have been submitted during the prosecution of the prior-filed application." 71 Fed. Reg. at 59-60 (proposed § 1.78(d)).

75. In NPRM 1, the PTO also proposed amending its rules of practice regarding RCE applications. One such proposal was to restrict applicants to a "single request for continued examination." Any additional requests would require the applicant to file a petition "showing to the satisfaction of the Director that the amendment, argument, or evidence could not have been submitted prior to the close of prosecution in the application." 71 Fed. Reg. at 61.

76. The PTO solicited comments on NPRM 1 and received a large number of comments in response. GSK submitted comments opposing many of the proposed rules set forth in NPRM 1 and arguing that the PTO lacked statutory authority for many of its proposed amendments.

77. The PTO did not hold any public hearings on the proposed rules set forth in NPRM 1. *See* 71 Fed. Reg. at 49.

b. In NPRM 2, The PTO Proposed Limiting Applicants Up To Ten "Representative Claims" And Requiring An Examination Support Document

78. In relevant part, NPRM 2 proposed amending the PTO's rules to allow an applicant to obtain examination of only claims designated by the applicant as "representative claims." If the applicant chose to designate more than ten independent claims or a combination of ten independent and dependent claims, then the applicant would have to provide an ESD. *See* 71 Fed. Reg. at 67-68 (proposed § 1.75)

79. In NPRM 2, the PTO proposed adding Section 1.261 to the Patent Office rules setting forth the requirements of the ESD, including, for example, a statement that a pre-examination search was conducted, an information disclosure statement citing the reference or references deemed most closely related to the subject matter of each designated claim, and for

each claim cited, identification of all limitations of the designated claims found in the reference or references. *See* 71 Fed. Reg. at 68-69.

80. The PTO solicited comments on NPRM 2 and received a large number of comments, albeit less than the PTO received with respect to NPRM 1. Many of the comments were unsupportive of the PTO's proposed action in NPRM 2. GSK submitted comments in response to NPRM 2 asserting that the PTO lacked statutory authority for its proposed limits on the number of claims an applicant would be permitted to file in an application without filing an onerous ESD.

81. The PTO did not hold any public hearings on the proposed rules set forth in NPRM 2. *See* 71 Fed. Reg. at 61.

ii. Comments In Response To NPRM 1 And NPRM 2

82. During the notice and comment period, the PTO received 114 and 73 comments on NPRMs 1 and 2, respectively, from GSK, intellectual property associations, government agencies, corporations, associations and law firms, as well as over 200 and 100 comments, respectively, from individuals. In other words, the PTO's proposed rulemaking generated over 500 comments in a highly technical area as to a rulemaking that the PTO couches as being merely procedural. Many of the comments submitted by professional organizations and business entities were extremely thorough, critiquing both the substance of the proposed rules and offering constructive alternatives. The general tenor of the comments submitted was as negative as the commentary was extensive, and almost uniformly so. While comments expressed sympathy with the logistical challenges facing the PTO and with its historic backlog, most stated that the proposed rules were not within the authority of the PTO to enact, would stifle innovation and the development of new technologies, and would in practice exacerbate the very backlog of patent applications the proposed rules were designed to alleviate.

83. The problems identified in the comments touched almost every proposed change offered by the PTO and concerned not only the lack of clarity such changes would bring to the application process, but the infeasibility of many of the changed rules in practice. Most notably, in terms of frequency and strength of conviction, the sentiment was forcefully expressed that the proposed rules were beyond the authority of the PTO and in many ways were inconsistent with, and in some cases implicitly rewrote important substantive provisions of the Patent Act. The predominant theme in the substantive criticism of the proposed rules was that the mechanisms offered by the PTO for avoiding the binding and arbitrary numerical limits being adopted, such as the submission of an ESD in the area of claims practice and the requirement that a filing make a showing "that the amendment, argument, or evidence sought to be entered could not have been submitted during the prosecution of the prior-filed application" in the area of continuation practice, were impractical to the point of being prohibitive. Also notable was criticism of the perverse incentives created by, and bizarre results that were likely to result from, adoption of the proposed changes.

H. The Final Rules

i. The Final Rules Substantively Change Continuing Application Practice

84. The Final Rules relating to continuing applications differ from those proposed in NPRM 1. Significantly, the PTO now allows a combination of no more than two nonprovisional continuing applications before requiring the applicant to submit a petition showing that the amendment, arguments, or evidence could not have been presented during the prosecution of the prior-filed application. *See* 72 Fed. Reg. at 46839. An application that cannot satisfy the "could not have been submitted" showing, loses the benefit of priority it was otherwise entitled to under 35 U.S.C. §§ 120, 121, or 365(c).

85. The Final Rules apply the provisions of newly amended 37 C.F.R. § 1.78(d), aside from (d)(1), retroactively. *Id.* at 46717. As to newly amended subsection (d)(1), the Final Rules apply to any application filed on or after November 1, 2007, which includes a continuing application claiming the benefit of an application filed before November 1, 2007. *Id.* at 46716-17.

86. Further, the newly amended subsection (d)(1) applies the petition requirement retroactively to second or subsequent continuing applications that claim the benefit under 35 U.S.C. §§ 120, 121, or 365(c) only of nonprovisional applications or international applications filed before August 21, 2007, if there is no other application filed on or after August 21, 2007 that also claims the benefit under 35 U.S.C. §§ 120, 121, or 365(c) of such prior-filed nonprovisional applications or international applications. The provision purports to "provide applicants with 'one more' continuation application or continuation-in-part application of a second or subsequent continuing application (continuation application or continuation-in-part application) that was filed prior to the publication date of this final rule in the Federal Register without a petition under § 1.78(d)(1)(iv)." 72 Fed. Reg. at 46736-37.

ii. The Final Rules Significantly Restrict The Number Of Claims An Applicant May Prosecute

87. In the Final Rules, the Director and PTO restrict the number of claims an applicant may file before being required to file an ESD. *See* 71 Fed. Reg. at 46836-37 (proposed § 1.75(b)). The Final Rules allow an applicant 5 independent claims or a total number of 25 claims in a single application before requiring the applicant to submit an ESD.

88. The Final Rules purport to apply the changes to 37 C.F.R. § 1.75 retroactively. Specifically, the Final Rules state that the changes to Section 1.75 apply "to any nonprovisional application filed under 35 U.S.C. 111(a) on or after November 1, 2007, and to

any . . . nonprovisional application filed before November 1, 2007, in which a first Office action on the merits was not mailed before November 1, 2007." 72 Fed. Reg. at 46716.

iii. The Final Rules Significantly Change RCE Practice

89. The Director and the PTO made significant changes to the PTO's practice relating to RCEs. Specifically, under newly amended § 1.114, an applicant is permitted only a single RCE in a patent family before being required to file a petition and "showing that the amendment, argument, or evidence sought to be entered could not have been submitted prior to the close of prosecution in the application . . . ." 72 Fed. Reg. at 46841. The changes to § 1.114 in the Final Rules are more extensive than those proposed by the PTO in NPRM 1.

90. The Final Rules apply newly amended 37 C.F.R. § 1.114 retroactively by requiring a petition and showing if an applicant files an RCE after November 1, 2007 but had previously filed an RCE in an application chain. 72 Fed. Reg. at 46717.

V. PRELIMINARY INJUNCTIVE RELIEF

91. To be entitled to a preliminary injunction, GSK must show: (1) that it is likely to succeed on the merits; (2) that it will be irreparably harmed; (3) that the balance of the hardships tips in its favor; and (4) the public interest is in its favor. *See Abbott Labs. v. Andrx Pharmas., Inc.*, 473 F.3d 1196, 1200-01 (Fed. Cir. 2007); *see also Blackwelder Furniture Co. v. Seilig Mfg. Co.*, 550 F.2d 189, 196 (4th Cir. 1977) ("[The] standard for interlocutory injunctive relief is the balance-of-hardship test . . . .").

A. Irreparable Injury

92. The Final Rules, if implemented, will irreparably injure GSK. First, GSK will be irreparably harmed by being required to comply with new patent regulations that are *ultra vires* because the PTO did not have the authority to promulgate them. Second, the Final Rules will diminish GSK's patent rights in its inventions by restricting its ability to file continuing

applications on inventions that were discovered and developed based on the current, well-established regulations. The Final Rules put at risk GSK's pending applications, including approximately one hundred or more pending applications in which two or more continuations or continuations-in-part have been filed, and approximately thirty or more pending applications in which two or more continuations or continuations-in-part and a request for continued examination have been filed. In almost all cases, GSK will be forced to confront a Hobson's choice, because it is unclear how an applicant and its counsel could satisfy both the applicable ethical obligations and the "could not have" standard. As a result, GSK's continuing applications may lose the benefit of their priority dates. This harms GSK because of the long research period during which it must test and further develop its drug products. GSK will also be irreparably harmed because it will not know how to organize its business; new 37 C.F.R. §§ 1.75 and 1.265 are vague and incomprehensible and it remains unclear whether and how GSK will identify a viable path to comply with the regulations.

93. Further, as described earlier, the Final Rules apply retroactively to pending applications. GSK has prosecuted these pending applications under well-established rules and tailored its business accordingly. GSK has filed multiple continuations, continuations-in-part, and RCEs relying on these well-established rules. By forcing GSK to accept less protection than GSK is entitled to under the law and under the well-established rules in place at the time these applications were filed, the retroactive application of Final Rules will cause irreparable injury to GSK.

94. Because the Final Rules truncate GSK's substantive patent rights, they put substantial investment capital at risk. If not preliminarily enjoined, then when the Final Rules are ultimately stricken as illegal and vague, it may be too late to save patent rights covering

medical inventions that can not proceed to market without strong proprietary protection. The drugs will be lost to both GSK and the public. Because GSK cannot sue the United States government for its lost patent protection, GSK will suffer irreparable harm if the Final Rules are implemented and later stricken.

B. Likelihood Of Success On The Merits

95. GSK is likely to prevail on the merits because, as explained below in Count I, the Final Rules' restrictions on patent applications are *ultra vires* because the PTO lacks the authority to promulgate substantive rules in the area. Moreover, GSK is likely to prevail because the PTO lacks statutory authority to restrict continuation applications in the manner set forth in the Final Rules (Count II); the Final Rules retroactively change legal consequences of already-filed continuation applications and patent prosecution strategies (Count III); the Final Rules' restrictions on the number of claims contradict the Patent Act (Count IV); the Final Rules' restrictions on requests for continued examination contradict the Patent Act (Count V); and the Final Rules are vague and incomprehensible (Count VII).

C. The Harm To GSK Outweighs The Harm To The PTO

96. In contrast to the irreparable harm GSK will suffer, the PTO will suffer little prejudice if the Final Rules are stayed pending the resolution of the merits of this case in a final judgment. Temporarily delaying the implementation of the Final Rules would maintain the status quo by leaving the PTO's current application examination process in place. That approach is well-established and understood by the PTO and applicants. On the other hand, the Final Rules have yet to be implemented and would require that GSK, and other applicants, make significant and radical changes in how they prosecute patents to account for the Final Rules' arbitrary and vague design.

97. Further, the PTO's reason for implementing these rules—improving efficiency by reducing the workload for examiners of applications—supports preliminarily enjoining the rules because, as the PTO admits, these proposed changes are not sufficient to address the underlying problem. 72 Fed. Reg. at 46756 ("The Office does not expect that the changes being adopted in this final rule alone will be sufficient to address the growing backlog of unexamined patent applications.").

D. A Preliminary Injunction Is In The Public Interest

98. The highest public interest is human health. It is in the public interest to insure that changes to the patent system do not cause a disincentive to GSK to bring more lifesaving drugs to market, or cause GSK to drop a research program on a lifesaving drug because of a loss of patent rights.

99. Because GSK has shown a high likelihood of success on the merits, and given that the Final Rules will have a substantial adverse affect on patent protection, the public will benefit by staying their implementation, and ultimately, upon final judgment, by vacating and enjoining those regulations.

CAUSES OF ACTION

FIRST COUNT

The Final Rules' Various Restrictions On Patent Application Rights Are All *Ultra Vires* Because The PTO Lacks The Authority To Issue Substantive Rules In This Area.

100. GSK re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 99 of this Complaint as though fully set forth herein.

101. The PTO's rulemaking powers are provided by 35 U.S.C. § 2(b)(2) and constrained by that statute. The Director is similarly constrained by those powers. *See* 35 U.S.C. § 3(a)(1).

102. Under Section 2(b)(2), the PTO is restricted to regulating the enumerated subjects, and those subjects alone. Moreover, the PTO and Director lack "any general substantive rule making power." *Merck*, 80 F.3d at 1549-50. Instead, even at their zenith, the rulemaking powers of the PTO and Director are directed only to governing "the conduct of proceedings in the [PTO]." *Id.*

103. The PTO cannot claim deference to construe provisions of the Patent Act that the agency was not explicitly conferred with the power to construe. Instead, the general design of the Patent Act is to make questions of construction of the Act questions delegated to courts to resolve. This is one reason Congress centralized review of cases involving constructions of the patent laws in the Federal Circuit in the Federal Courts Improvement Act. *See In re Lueders*, 111 F.3d 1569, 1577 (Fed. Cir. 1998) ("[T]he Federal Courts Improvement Act was a significant venture . . . , it consolidated in this court, the Court of Appeals for the Federal Circuit (CAFC), nationwide jurisdiction over all appeals from patent cases in the district courts in addition to the CCPA's existing jurisdiction over direct appeals from the PTO boards.").

104. Deference to agencies under the familiar test of *Chevron U.S.A., Inc. v. NRDC*, 467 U.S. 837 (1984) is impermissible where Congress has conferred the power to construe the relevant provisions of one of its enactments exclusively upon the courts and not upon an agency. *See Adams Fruit Co. v. Barrett*, 494 U.S. 638, 649 (1990) ("A precondition to deference under *Chevron* is a congressional delegation of administrative authority."). Here, the PTO is not owed any *Chevron* deference because Congress did not grant the PTO with authority to generally and authoritatively construe the provisions of the Patent Action (except where specifically enumerated).

105. As written by Congress, the patent laws do not, among other things, limit or restrict the number of continuing applications, RCEs, or claims that may be filed. They do not grant the Director the authority or discretion to limit those filings; nor do they grant the Director authority to impose retroactive limitations. Rather, the patent laws provide narrowly defined powers to the Director so that the Director can facilitate the allowance of applications that satisfy the conditions for patentability. Contrary to these clear limits long observed by the PTO and its predecessor agencies, the current PTO interprets its power under 35 U.S.C. § 2(b)(2)(C) to "facilitate and expedite the processing of patent applications" to allow it to redefine the statutory rules concerning continuing applications, RCEs, and claims filing. The PTO lacks any such power.

106. The Final Rules add a significant and uncertain burden to GSK. Specifically, they threaten to diminish greatly the value of GSK's pending and future patent applications by depriving GSK the ability to claim fully and completely its inventions. GSK conducts research and development and invests billions of dollars with the expectation that its discoveries will be fully protected by the patent laws. Further, GSK has disclosed inventions to the public with the expectation that it will be given the opportunity to patent the fruits of its continued research and development efforts by, for example, prosecuting in good faith continuation applications under 35 U.S.C. § 120. Because the Final Rules cut back on the protections Congress granted to patentees in the patent laws, GSK and other similarly situated applicants will be denied the full protection afforded by those laws.

107. By issuing final regulations that set forth binding and mandatory rules that limit unlawfully the number of continuation, continuation-in-part, divisional and related applications, requests for continued examination, and claims that may be filed, the Director and PTO have

acted in a manner "not in accordance with law," and "in excess of statutory jurisdiction and authority," 5 U.S.C. § 706, running afoul of 35 U.S.C. §§ 2, 120, 131, 132, and 365. Under the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*, a reviewing court has a duty "to hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706.

SECOND COUNT

The PTO Especially Lacks The Authority To Impose The Final Rules' New Restrictions Concerning Continuing Applications.

108. GSK re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 99 of this Complaint as though fully set forth herein.

109. The PTO lacks the authority to limit the number of continuation applications that applicants can file. *See Henriksen*, 399 F.3d at 254. Under Section 120 of the Patent Act, the Director is mandated to accept any continuing application that meets the stated formal conditions and award the applicant the filing date of the prior filed application.

110. The Final Rules limit GSK to only two continuation applications that enjoy the benefit of a priority filing date because the PTO, in responding to comments, indicated it is unlikely to grant a petition 37 C.F.R. § 1.78(d)(iv) in all but one case (where an applicant diligently acquires data demonstrating unexpected results and desires to submit the data to rebut a new PTO rejection that the claims are obvious over the prior art). Given the PTO's construction of the "could not have been submitted" previously standard for the petition, it remains unclear whether and how a petition can be filed without implicating potential noncompliance with another patent regulation, 37 C.F.R. § 10.85, which exposes GSK to great damage.

111. In an attempt to avoid *Henriksen*, the PTO characterizes its Final Rules as not imposing an absolute limit of two continuing applications. 72 Fed. Reg. at 46756. However, the PTO's responses to comments demonstrate that the Final Rules impose a de facto limit of two continuing applications because the PTO has indicated it will deny a petition for a third continuing application in almost all circumstances. *See* 72 Fed. Reg. at 46769-77.

112. In view of this, the PTO's petition requirement is illusory and is a thinly-veiled attempt to circumvent Section 120.

113. Moreover, the Court cannot tolerate the PTO's circumvention of the terms of Section 120 because the PTO cannot accomplish indirectly that which Congress has prohibited it from achieving directly. *See, e.g.*, *Industrial Union Dep't, AFL-CIO v. Bingham*, 570 F.2d 965, 976 (D.C. Cir. 1977); *cf. U.S. Term Limits v. Thornton*, 514 U.S. 779, 829 (1995) ("The Constitution nullifies sophisticated as well as simple-minded modes of infringing on constitutional protections.") (internal quotation marks omitted).

114. The PTO's obvious misperception of the limits of its statutory authority when enacting the Final Rules also renders its amendments to the continuation application ground rules arbitrary and capricious. *See Prill v. NLRB*, 755 F.2d 941, 942 (D.C. Cir. 1985) ("erroneous conception of the bounds of the law" by an agency require arbitrary and capricious action premised on such an error to be vacated and remanded for the agency to act consistent with the true bounds of the law).

115. The PTO invokes an administrative efficiency rationale in an attempt to justify its new limitations on continuing applications. According to the PTO, limiting the number of continuing applications will reduce the strain on patent examiners and help to clear the PTO's backlog of pending patent applications. *See* 72 Fed. Reg. at 46752.

116. Even if the final Rules were authorized, which they are not, the PTO's backlog rationale is arbitrary and capricious. The PTO did not adequately explain the rationale, the PTO ignored less-drastic and less-damaging alternatives to eliminating abusive continuation applications (it cannot be denied such alternatives were offered in the comment process), and the PTO's own statistics demonstrate that the continuation application limitations will have a negligible effect on the backlog, at best. Indeed, the PTO itself states that less than 2.7% of applications filed in fiscal year 2006 were a third or subsequent continuation or continuation-in-part application. *See* 72 Fed. Reg. at 46756. Hence, the PTO cannot meaningfully hope to reduce its backlog by revising the continuing-application process.

117. Further, the rules illegally apply retroactively to already pending applications.

118. By restricting statutory continuation application rights and by failing to justify the new rules governing continuation applications, the Director and PTO have acted in a manner "not in accordance with law," and "in excess of statutory jurisdiction and authority." 5 U.S.C. § 706, running afoul of 35 U.S.C. §§ 2, 120. Consistent with the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*, a reviewing court has a duty "to hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" or "arbitrary and capricious." 5 U.S.C. § 706.

THIRD COUNT

The Final Rules Are Beyond The PTO's Power Because They Retroactively Change The Legal Consequences Of Already Filed Continuation Applications And Patent Prosecution Strategies.

119. GSK re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 99 of this Complaint as though fully set forth herein.

120. Congress did not explicitly grant the PTO retroactive rulemaking powers in 35 U.S.C. § 2(b)(2) and, thus, the PTO lacks such power. *See Bowen v. Georgetown Univ. Hosp.*,

488 U.S. 204, 208 (1988); *see also Leland v. Fed. Ins. Admin.*, 934 F.2d 524, 527 (4th Cir. 1991).

121. In applying the Final Rules retroactively in certain respects, the PTO exceeded its authority. For instance, the Final Rules' restriction on continuation applications will apply to applications pending on November 1, 2007. Continuation applications that have already exceeded the new ceiling of two such applications will be permitted only one more such application as of right. *See* 72 Fed. Reg. at 46826.

122. The PTO argues that applying the Final Rules to existing applications is not retroactive because the agency is merely applying its new rules to a pending case, citing *Landgraf v. USI Film Prods.*, 511 U.S. 244, 255 (1994), and citing cases involving the FCC where the D.C. Circuit held that applications for licenses did not create vested property rights. *See, e.g.*, *Community TV, Inc. v. FCC*, 216 F.3d 1133, 1143 (D.C. Cir. 2000). The PTO neglects to cite any patent application cases and with good reason. "It is now well settled that patent applications are property." *Winchester*, 1933 WL 231, at 3; *see also Ruckelshaus*, 467 U.S. at 1002-04 (finding that intellectual property, such as a trade secret, is constitutionally protected private property). Hence, changes to the rules on patent applications mid-stream—while such applications are pending—are inherently retroactive, and thus unlawful under *Bowen*.

123. By applying amended rules to pending patent applications in various respects, the Director and PTO have acted in a manner "not in accordance with law," and "in excess of statutory jurisdiction and authority," 5 U.S.C. § 706, under the Supreme Court's retroactivity law severely restricting agency powers to engage in rulemaking of that nature. Under the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*, a reviewing court thus has a duty "to hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or

limitations, or short of statutory right." 5 U.S.C. § 706. Accordingly, all aspects of the Final Rules that apply to pending applications must be set aside and enjoined.

FOURTH COUNT

The PTO Lacks The Authority To Restrict The Number of Claims That Can Be Presented In A Patent Application.

124. GSK re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 99 of this Complaint as though fully set forth herein.

125. The Final Rules restrict the ability of GSK, and other applicants, to a limited number of claims, i.e., a maximum of five independent and/or twenty-five total claims (without filing the onerous ESD). Further, the rules apply retroactively to certain applications. These limitations, and their retroactive application, exceed the bounds of Congress' grant of authority. *See* 35 U.S.C. § 111(a)(2), § 112, ¶ 2. These sections do not remotely provide the Director with authority or discretion to limit the number of claims an applicant may file.

126. The PTO, again, invokes an administrative efficiency rationale in attempting to justify its new restrictions on the number of claims that an applicant may file. As with the continuation application rules, the PTO's efficiency rationale is similarly arbitrary and capricious here because it is unsupported by data and insufficiently explained. In particular, the PTO failed to consider the dynamic effects that its rules limiting the number of claims would have on patent applications. For instance, commenters explained that restricting the number of claims would simply result in dividing what would have been filed as one application into multiple applications, which would counterproductively increase the number of patent applications, and thus do nothing to reduce the PTO's backlog of unaddressed applications.

127. While the PTO imposes other restrictions designed to prevent dividing patent applications and to restrict continuing applications, the Final Rules, when taken as a whole, will

have the effect of precluding the filing of some perfectly meritorious claims to invention. The PTO lacks the authority to refuse to examine claims, nor has it provided an adequate explanation for doing so. *See* 35 U.S.C. §§ 111, 112, 131.

128. The PTO may explore the goal of increasing its efficiency in processing applications, but may not limit the number of claims to reduce its backlog. Section 2(b)(2)(C) grants the PTO the power to seek greater efficiencies, but restricting rights to pursue valid claims under other provisions of the Patent Act is not a power available to the PTO because that is "inconsistent with law"—i.e., with other provisions of the Act beyond Section 2. Hence, the Final Rules are both *ultra vires* under the Patent Act and arbitrary and capricious.

129. By restricting the number of claims that can be filed by patent applicants, the Director and PTO have acted in a manner "not in accordance with law," and "in excess of statutory jurisdiction and authority," 5 U.S.C. § 706, running afoul of 35 U.S.C. §§ 2, 111, 112, and 131. Under the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*, a reviewing court has a duty "to hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" or "arbitrary and capricious." 5 U.S.C. § 706.

FIFTH COUNT

Restrictions In The Final Rules On the Rules For Continued Examinations Are Contrary To The Patent Act.

130. GSK re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 99 of this Complaint as though fully set forth herein.

131. The Final Rules restrict the ability of GSK and other applicants to file RCEs. Amended Section 1.114 limits an applicant to only one RCE in a patent application family (without the need for filing a petition and making a specified showing), which runs afoul of the

express language of 35 U.S.C. § 132(b). Section 132(b) requires the Director to continue examining the application at the request of the applicant. Further, Section 1.114 applies retroactively to pending applications.

132. In enacting § 132, Congress did not grant the Director the authority to restrict or the discretion to refuse to continue examining an application after receiving an applicant's RCE. Accordingly, the PTO has overstepped its congressionally authorized powers in promulgating limitations on RCEs.

133. By restricting the process for requesting continued examinations (i.e., the process for RCEs), the Director and PTO have acted in a manner "not in accordance with law," and "in excess of statutory jurisdiction and authority," 5 U.S.C. § 706, violating the Patent Act, 35 U.S.C. §§ 2 and 132. Under the Administrative Procedure Act, 5 U.S.C. § 551, *et seq.*, a reviewing court has a duty "to hold unlawful and set aside agency action" that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706.

SIXTH COUNT

The Final Rules Are Procedurally Defective In Various Respects For Failure To Provide A Required Notice And A Comment Opportunity Before The Proposed Regulations Were Amended In Ways That Could Not Reasonably Have Been Anticipated.

134. GSK re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 99 of this Complaint as though fully set forth herein.

135. In NPRM 2, the PTO proposed restricting applicants to ten representative claims, whether all independent or a combination of independent and dependent claims, that would be examined before triggering the requirement of filing an ESD. The PTO did not propose limiting the total number of independent and dependent claims an applicant could file in a single application without triggering such a requirement.

136. Despite widespread opposition registered in the comments received by the PTO to creating such arbitrary numerical thresholds before the onerous ESD requirement would be triggered, the Final Rules impose even more stringent restrictions: reducing to five the number of independent claims and placing a completely new restriction (at twenty-five) on the total number of claims that could be filed in an application before the examination support document requirement would be triggered.

137. In light of the initial notice, interested parties could not have anticipated an increase in the restriction on the number of claims, particularly in view of the widespread opposition to the proposal in NPRM 2. The new standards were not a logical outgrowth of the initial rulemaking and therefore provided inadequate notice to satisfy the 5 U.S.C. § 553(b) requirement that "general notice of proposed rule making shall be published in the Federal Register."

138. Final rules that are not logical outgrowths of proposed agency rules deprive the public of the notice the APA requires for the purpose of permitting intelligent and targeted comments to be filed expressing concerns with any agency proposal. Hence, final rules that are not true logical outgrowths of proposed rules effectively sandbag the regulated public. Accordingly, the PTO's rules limiting the number of claims represent procedural violations of the notice requirement for rulemaking in the APA. *See* 5 U.S.C. § 553(b). Thus, the PTO's limitations on the number of claims must be invalidated because they were promulgated "without observance of procedure required by law." *See* 5 U.S.C. § 706(2)(D) (authorizing the setting aside of agency regulations issued in procedurally defective ways).

SEVENTH COUNT

The Final Rules Are Vague And Do Not Put GSK On Sufficient Notice Of How To Comply.

139. GSK re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 99 of this Complaint as though fully set forth herein.

140. The Final Rules are so vague that they are incapable of being complied with and do not put GSK on sufficient notice of what it must do to comply. Under new 37 C.F.R. § 1.75(b)(1), if an application contains more than five independent claims and/or twenty-five total claims, an applicant must file an ESD in compliance with new 37 C.F.R. § 1.265. 72 Fed. Reg. at 46836.

141. Newly created § 1.265 sets forth the requirements of an ESD, one of which, § 1.265(a)(1), requires that the applicant perform a preexamination search. *Id*. at 46842. Rule 1.265(b) sets forth requirements of a preexamination search as including the searching of "U.S. patents and patent application publications, foreign patent documents and non-patent literature." *Id*.

142. Newly added § 1.265(b), however, does not provide any metes or bounds on the scope of the search and, as a result, GSK cannot be certain about how to comply with this regulation. For instance, the rule does not indicate whether the applicant must conduct electronic searches, manual searches, or both; in which countries databases the applicant must search; or which libraries it must search. Certainly, the cost of searching could be quite large and the rule does not set forth an expense cap or limitation. In light of the vagueness of § 1.265, GSK does not know how to comply with the rule and, therefore, the PTO should be enjoined from implementing the rule.

143. In another example, 37 C.F.R. § 1.75 directs that "[m]ore than one claim may be presented provided they differ substantially from each other and are not unduly multiplied." The

term "not unduly multiplied" in the regulation is also incomprehensible and does not put GSK on notice of what is permissible. This kind of vague language can impermissibly be used at the discretion of the PTO to mean almost anything, and therefore is not a well-defined regulation capable of compliance or organization of business activities.

144. Specifically, by issuing final regulations that are vague and indefinite and thereby "either forbid[] or require[] the doing of an act in terms so vague that men of common intelligence must necessarily guess at its meaning and differ as to its application," *United States v. Lanier*, 520 U.S. 259, 265 (1997), the Director and PTO have acted in a manner "contrary to constitutional right, power, privilege, or immunity," 5 U.S.C. § 706, under the Fifth Amendment of the Constitution, entitling GSK to an injunction against implementation of the Final Rules.

EIGHTH COUNT

The Final Rules Work An Unconstitutional, *Ultra Vires*, And Arbitrary And Capricious Taking Of GSK's Patent And Patent Application Property Rights.

145. GSK re-alleges and incorporates by reference the allegations set forth in paragraphs 1 through 99 of this Complaint as though fully set forth herein.

146. Patents and patent applications are constitutionally protected private property. *See* 35 U.S.C. § 261; *Consolidated Fruit-Jar*, 84 U.S. at 96 ("A patent for an invention is as much property as a patent for land."); *Winchester*, 1933 WL 231, at 3 ("It is now well settled that patent applications are property."); *Ruckelshaus*, 467 U.S. at 1002-04 (finding that intellectual property, such as a trade secret, is constitutionally protected private property).

147. In barring GSK from filing more than two continuation applications through the use of a petition, and effectively restricting GSK to no more than five independent and twenty-five total claims because the ESD requirement is vague, incomprehensible and potentially incapable of being complied with, the Final Rules operate to destroy GSK's patent rights in those

inventions. Accordingly, the Final Rules operate as a per se taking of GSK's property rights. *See Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1019-20 (1992).

148. The Final Rules also significantly impact GSK's reliance interests and its valid expectations following the investment of sizable sums of capital. GSK has invested significantly in the research and development of pharmaceuticals. It is unquestionable that pharmaceutical companies devote billions of dollars in research and developing pharmaceuticals. GSK's development cycle is lengthy. To protect its investment, GSK relies heavily on patents and patent applications, including continuation patent applications. GSK has disclosed inventions to the public in its patent applications with the expectation that it will be afforded the opportunity to patent the fruits of its continued research and development efforts through the vehicle of continuation applications under 35 U.S.C. § 120.

149. The Rules substantially impact GSK's expectations because the Final Rules abridge substantially GSK's ability to protect its continuing research efforts by curtailing its ability to file continuation patent applications. The Final Rules further vitiate GSK's expectations by restricting its ability to file continuing applications, requests for continued examination, and ability to file more than five independent and/or twenty-five total claims.

150. Hence, the Final Rules, if they are allowed to become effective, will effectively wipe out significant capital investments made in reliance on the existing patent application system and thereby alter the preexisting property rights under the Patent Act, threatening an unconstitutional taking.

151. The PTO was informed about the takings issues raised by its Final Rules, yet decided to proceed with them anyway without completely or adequately addressing those concerns. Hence, the rules on continuation patents as applied to patents initially filed before the

effective date of the Final Rules are arbitrary and capricious. *See, e.g.*, *NWF v. ICC*, 850 F.2d 694, 705-06 (D.C. Cir. 1988); *NWF v. Hodel*, 839 F.2d 694, 750-51 (D.C. Cir. 1988); *see also Motor Vehicles Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983) (an agency rule is arbitrary and capricious "if the agency . . . has entirely failed to consider an important aspect of the problem."). Therefore, the retroactive provisions in the Final Rules must be set aside under Section 706(2) of the Administrative Procedure Act.

152. Additionally, agencies lack the power to exercise the federal government's eminent domain powers unless and until they have been delegated such power. *See, e.g.*, *United States v. Parcel with Improvements Thereon in Square South of 12, D.C.*, 100 F. Supp. 498, 504 (D.D.C. 1951) ("While the power of eminent domain is an inherent right of sovereignty, it is not open to question that such power lies dormant until legislative action is had pointing out the occasions, modes, agencies and conditions for its exercise.") (relying on 1 *Nichols on Eminent Domain*, 3d ed., 203, § 3.2, *citing Secombe v. Railroad Co.*, 90 U.S. (23 Wall.) 108 (1874)).

153. Because the PTO lacks the power to issue substantive rulemakings, it similarly lacks the power to engage in takings of any kind (whether regulatory or physical). Congress has simply not conferred that power on the PTO. Hence, the PTO's regulations cannot be permitted to diminish or disparage property rights in patent applications, and because the Final Rules do so, they must be enjoined. Specifically, by issuing final regulations that set forth binding and mandatory rules that limit unlawfully the number of continuing applications, requests for continued examination, and claims that may be filed, the Director and PTO have acted in a manner "contrary to constitutional right, power, privilege, or immunity," 5 U.S.C. § 706, under the Fifth Amendment of the Constitution, entitling GSK to an injunction against implementation of the Final Rules.

PRAYER FOR RELIEF

WHEREFORE, GSK prays for judgment against Defendants as follows:

A. Maintain the status quo and grant a preliminary and permanent injunction enjoining and staying implementation of the Final Rules pending resolution of this lawsuit.

B. Grant a permanent injunction enjoining Defendants from issuing new regulations limiting the number of continuing applications, requests for continued examination, and the number of claims that may be filed with the PTO that are deficient in any of the ways described in this complaint, or otherwise infringes GSK's rights in the manner described in this complaint.

C. Enter a declaratory judgment that the Final Rules are, in the respects denoted above, vague, arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law (including but not limited to the Patent Act), contrary to constitutional right, power, privilege or immunity, and in excess of statutory jurisdiction, authority or limitations.

D. Vacate the Final Rules as arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law (including but not limited to the Patent Act), contrary to constitutional right, power, privilege or immunity, and in excess of statutory jurisdiction, authority or limitations.

E. Issue any writs of mandamus necessary to compel the PTO to perform neglected or unlawfully unperformed duties.

F. Order such other and further relief as the Court deems appropriate.

Date: October 11, 2007

Respectfully submitted,

/s/

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VERIFICATION

I, Sherry M. Knowles, of full age, being duly sworn according to the law, upon her oath deposes and says:

I am Senior Vice President and Global Head of the Corporate Intellectual Property of SmithKline Beecham Corporation, doing business as GlaxoSmithKline, Glaxo Group Limited, doing business as GlaxoSmithKline, and SmithKline Beecham plc, the plaintiffs in the above matter. I have reviewed the allegations made in this Verified Amended Complaint and they are true and accurate to the best of my knowledge and belief.

I declare under penalty of penalty of perjury that the foregoing is true and correct.

Executed this 11th day of October 2007.

/s/________________________
Sherry M. Knowles